U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

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Re: Children's Toy Jewelry Containing Lead

Dear Manufacturer, Importer, Distributor, Retailer:

The U.S. Consumer Product Safety Commission (CPSC) is an independent federal regulatory agency responsible for protecting the public from unreasonable risks of injury and death associated with consumer products. The purpose of this letter is to urge manufacturers, importers, distributors and retailers of children's toy jewelry to assure that the jewelry does not contain accessible lead and preferably, does not contain any lead. In this letter, we also explain how CPSC staff tests for lead in toy jewelry.

The Hazard

Recently, CPSC staff collected and analyzed some items of toy metal jewelry sold in vending machines and concluded that children who use the items could be exposed to high levels of accessible lead and that the lead presented a lead poisoning hazard. As a result, CPSC staff determined these products were banned hazardous substances under the Federal Hazardous Substances Act and obtained voluntary recalls of the children's toy jewelry. Children who wear the recalled toy jewelry can ingest the lead by handling the lead containing jewelry and putting their hands in their mouths, by directly mouthing the jewelry, or by ingesting either parts or whole pieces of the jewelry.

The adverse health effects of lead poisoning in children are well-documented and may have long-lasting or permanent consequences. These effects include neurological damage, delayed mental and physical development, attention and learning deficiencies, and hearing problems. Because lead accumulates in the body, even exposures to small amounts of lead can contribute to the overall level of lead in the blood and to the subsequent risk of adverse health effects. Therefore, any unnecessary exposure of children to lead should be avoided. The scientific community generally recognizes a level of 10 micrograms of lead per deciliter of blood (10 µg/dL) as a threshold level of concern with respect to lead poisoning. To avoid exceeding that level, the CPSC staff suggests that young children should not chronically ingest more than 15 micrograms of lead (15 µg) per day from consumer products. The staff uses 15-30 days as a surrogate for a chronic time period.

The Law

Under the Federal Hazardous Substances Act (FHSA), 15 U.S.C. § 1261(f)(1), household products that expose children to hazardous quantities of lead under reasonably foreseeable conditions of handling or use are "hazardous substances." A toy or other article intended for use by children, such as toy jewelry, which contains a hazardous amount of lead that is accessible to children and may cause substantial personal injury or illness through handling or use, including ingestion, is a banned hazardous substance. 15 U.S.C. § 1261(q)(1)(A). A household product that is **not** intended for children but which creates such a risk of injury because it contains lead requires precautionary labeling under the Act. 15 U.S.C. § 1261(p).

In January 1998, the Commission issued a policy statement on lead, "Guidance for lead (Pb) in consumer products." 16 C.F.R. § 1500.230. In this guidance document, the Commission identified the major factors it considers when evaluating the hazard of products that contain accessible lead. In addition, the Commission requested that firms eliminate the use of lead in consumer products or, if firms believe it is necessary to use lead, they should perform the requisite analysis before distribution to determine whether the exposure to lead causes the product to be a "hazardous substance." 16 C.F.R. § 1500.230(c)(4).

Testing and Analysis

The CPSC Laboratory Sciences staff conducts a number of tests on children's jewelry to estimate lead exposure. First, a CPSC chemist determines the total lead content of the product by dissolving it in two milliliters of concentrated nitric acid following the general procedure as described by the Association of Official Analytical Chemists (AOAC) in their *Official Methods of Analysis*, Vol. 1, method 974.02. The chemist conducts three additional tests to determine if the lead is accessible to children. These tests are a wipe test, a saline extraction test, and an acid extraction test.

Wipe Test

The chemist conducts the wipe test to estimate the exposure to lead from hand-to-mouth behavior (i.e., lead may be transferred from the product to the child's hands and subsequently be transferred to the child's mouth through normal hand-to-mouth activity). The chemist gently wipes accessible parts of the jewelry ten times each with three moist Ghost Wipes® (Environmental Express). Wiping is done in one direction over the accessible surface. After each wiping, the three wipes are then placed in separate test tubes and digested in 2 milliliters of concentrated nitric acid and refluxed for six (6) hours. The samples are analyzed as described at AOAC 974.02.

Saline Test

The saline test simulates lead exposure that may occur due to the action of saliva when a child mouths the toy jewelry. To conduct this test, the CPSC chemist weighs out the entire pendant, chain, ring, or bracelet and places it in a flask. The chemist adds 0.9 % saline solution (NaCl) (volume in milliliters equals 50 times the weight of the sample in grams). Extraction is done for 1 hour at 37° C in a shaker bath. After 1 hour, this saline solution is taken out and replaced with the same amount of fresh saline. Extraction is conducted for an additional 2 hours. Again the extracted solution is taken out and replaced with the same amount of saline. Extraction is done for an additional 3 hours and the extract is removed. Each of the three extracted solutions is individually analyzed for lead content with an ICP spectrometer. The

results are totaled for the three solutions. The result is expressed in µg of lead per gram (g) of metal or µg/g.

Acid Test

The acid test simulates lead exposure that may occur due to the action of stomach acid on a piece of jewelry or parts of jewelry subsequent to ingestion. To conduct this test, the CPSC chemist weighs the entire piece of jewelry and places it in a flask. The chemist adds 0.07 N hydrochloric acid (HCl) (volume in milliliters equals 50 times the weight of sample metal piece in grams). Extraction is conducted for 1 hour at 37° C in a shaker bath. After 1 hour, this acid solution is taken out and replaced with the same amount of a fresh 0.07 N HCl solution. Extraction is conducted for an additional 2 hours. Again the extracted solution is taken out and replaced with the same amount of 0.07 N HCl solution. Extraction is conducted for an additional 3 hours and the solution is removed. Each of the three extracted solutions is individually analyzed for lead content with an ICP spectrometer. The results are totaled for the three solutions. The result is expressed in µg of lead per gram of metal or µg/g.

A 6-hour extraction is analytically practical and was chosen to represent dynamic conditions of mouthing or swallowing. The 6-hour extraction methodology, consisting of separate extractions of 1, 2, and finally 3 hours, was chosen to represent the dynamic conditions of either mouthing (saline extraction represents saliva) or swallowing (acid extraction represents gastric juice). In both cases, the staff assumes that the lead extracted from the piece by body fluids is subsequently absorbed into the body, and that the body's sources of saliva and stomach acid act continually to extract additional lead from the piece.

Risk Assessment

CPSC health scientists use the laboratory analytical results along with guidance on human interactions and use characteristics information to estimate lead exposure from all likely exposure routes. CPSC health scientists and human factors staff assess each product on a case-by-case basis using all available data and their professional judgment. If children may be exposed to accessible lead from a non-painted toy or children's product and the lead exposure presents a substantial health risk to the child, the Office of Compliance considers the product to be a hazardous substance and, therefore, automatically banned under the FHSA. 15 U.S.C. § 1261(q)(1)(A). The sale, manufacture for sale, offer for sale in commerce, or importation of any banned hazardous substance is a prohibited act under section 4 of the FHSA, 15 U.S.C. § 1263 and could subject a firm to the penalties outlined in section 5 of the FHSA, 15 U.S.C. § 1264. Firms and individuals could be subject to civil fines of up to $1.65 million. Firms and individuals are also subject to criminal penalties.

Paint and Similar Surface Coating Materials

In addition to its concern with children's products that contain elemental lead, the Commission has, by regulation, banned paint and other similar surface-coating materials for consumer use that contain more than 0.06% lead. 16 C.F.R. Part 1303. Also, the Commission has banned toys and other consumer products that bear paint with more than 0.06% lead by weight. 16 C.F.R. § 1303.1(a).

Ensuring Compliance

To assure that their toys and children's products comply with current CPSC mandatory and industry voluntary standards, firms should establish good manufacturing practices. The Commission staff recommends that all firms establish quality assurance programs to ensure that all toys and children's products are correctly age graded, designed with child safety in mind, and include appropriate in-line and finished product testing. The quality assurance program should also include a careful review of all consumer safety-related complaints and injuries. Unsafe products must be reported to the Commission as required by section 15(b) of the Consumer Product Safety Act, 15 U.S.C. § 2064(b).

Sincerely,

Alan H. Schoem